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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,892	07/09/2001	Stephen Carl McKeown	PG3576USW	7728

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 11/03/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,892

Applicant(s)

McKeown et al

Examiner

Maurie G. Baker, Ph.D.

Art Unit

1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 13, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. The Response filed August 13, 2003 (Paper No. 11) is acknowledged. Claims 1-31 and 33-37 were cancelled, claim 32 was amended and no claims were added. Therefore, claim 32 is pending and under examination.

Status of Objections & Rejections

2. The objection to claim 32 as well as the previous rejections under 35 U.S.C. 112, second paragraph are withdrawn in view of applicant's claim amendments. The rejection under 35 U.S.C. 102(b) is also withdrawn in view of applicant's amendments to claim 32. However, new rejections, necessitated by applicant's claim amendments, are set forth in this action, see below.

New Rejections – Necessitated by Amendment Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - A. Claim 32 has been amended to include recitations regarding a second cleavage site within groups Y¹ and/or Y², a chemical fragment (Fr) and a sensitizing

group (G). It is completely unclear and confusing what the purpose of these moieties are in the context of the instant invention. The instantly claimed invention is a method of “differential release” that contains steps of testing substrate R released from group Y^1R and then releasing and testing substrate R from group Y^2R . There is nothing in the claimed method’s steps that relates to a second cleavage site within groups Y^1 and/or Y^2 , a chemical fragment (Fr) and a sensitizing group (G). Applicant is directed to MPEP 2173.05(a): [t]he meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed.

- B. The claim recites the phrase “e.g.”. This phrase renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
- C. Also, the claim recites that “(i)the chemical fragment Fr contains a sensitising group G which sensitises the chemical fragment Fr to instrumental, e.g. mass spectroscopic analysis and/or: (ii) the fragment Fr contains a means for imparting a characteristic signature to the mass spectrum of the fragment”. These recitations are unclear and highly confusing. First, it is unclear how these two choices are different from each other and second, it is unclear exactly what is meant to be encompassed by these recitations. It appears that the claim is incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections and/or for omitting essential steps, such

omission amounting to a gap between the steps. See MPEP § 2172.01.

Moreover, considering the fact that it is completely unclear what the purposes of these moieties are in the claimed method (see A above), the lack of definition (i.e. clarity) of such renders the claim indefinite.

New Rejections – Necessitated by Amendment
Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 32 is rejected under 35 U.S.C. 103(a) as obvious over Carrasco et al (Tet. Lett. 1997; on PTO-1449) in view of Lebl et al (US 5,635,598; of record).

Note that the claim is extremely unclear due to the many issues under 35 U.S.C. 112, second paragraph. The claim has been broadly interpreted to the best of the examiner's ability in the formation of this rejection as described in detail below.

Carrasco et al teach "direct monitoring of organic reactions on solid supports" using resin-bound constructs having a linker with two different cleavage sites attached thereto. See, for example, title, Abstract and Figure 1 of the reference. The constructs of Carrasco et al contain a "desired organic substrate" reading on R and an "ionization sequence" (see Figure 1, Scheme 1 and Abstract). The "derivatized resin" of Carrasco et al incorporates a "dual linker strategy" where the "combination of the photocleavable linker and the ionization tag enables direct analysis of the beads by MALDI-MS" (reading on the claimed Fr group comprising a "sensitising group G" and/or a "means for imparting a characteristic signature to the mass spectrum of the fragment"). The two linkers of the reference are separated by a spacer group (i.e. ionization sequence). The two linkers of Carrasco et al are photocleavable and chemically (acid) cleavable, respectively.

Although the definition of such in the claims is unclear, it does not appear that Carrasco et al teaches an assay method using a resin having groups specifically reading on Y^1R and Y^2R . It is noted that it appears that Carrasco et al teaches use of a resin having a moiety that could be defined as RY^1GY^2 .

However, the use of differently cleavable linkers specifically reading on the claimed Y^1R and Y^2R format in the analysis of resin bound constructs was well established in the art at the time of filing. For example, Lebl et al disclose solid phase supports having a variety of differently cleavable linkers attached thereto. See, for example, patented claims 1, 4, 6, 12, 16, 18 & 20-47. Lebl et al disclose “multiply cleavable linkers, in which cleavage of each linker is independent of the cleavage of the others...thus providing for sequential cleavage of the same or different peptide species from a solid support” (column 3, lines 9-15). Specific information for the first and second cleavage reactions is set forth, e.g., in column 3 of the reference, lines 20-67 (see also Section 5.2 beginning in column 11). Specifically, Figure 8 of Lebl shows a set-up where three differently cleavable sites are shown, as well as a fourth site with a coding tag. This reads directly on the claimed solid support having linked thereto groups Y^1R and Y^2R that are differentially releasable. The reference also states that a “releasable linker” releases “peptides to a solution compatible with biological tests” (column 3, lines 5-9). The peptides of Lebl read on the claimed substrate (R). Specific information for the biological testing of the peptides are described in many places in Lebl, see, for example, Section 5.4 in column 14. Testing of libraries using the multiple cleavable linkers of the reference is described in Section 5.4.1; see particularly column 15, lines 12-53 and the examples starting in column 15, line 54, e.g. example denoted (iii).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to perform the method of Carrasco et al on a resin bound construct that contains differently cleavable linkers specifically reading on the claimed Y¹R and Y²R format. This is because Lebl clearly describes the use of such linkers and that sequential cleavage of the same or different species from a solid support is advantageous. One of ordinary skill would have been motivated to combine the methods of Carrasco et al and Lebl in order to use common methodology for testing such as mass spectroscopy.

Status of Claims/Conclusion

8. No claims are allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached on (703) 306- 3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
October 29, 2003



MAURIE GARCIA BAKER PH.D
PRIMARY EXAMINER